DEC 31 2013

AOS
ADVANCED ORTHOPAEDIC SOLUTIONS

8. SPECIAL 510(K) SUMMARY

SUMMARY PREPARED ON: December 23, 2013

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

CONTACT PERSON:
Kazunori Miyahara
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME:
AOS Antegrade and Retrograde Femoral Nails
AOS Humeral Nails
AOS Tibial Nails
AOS Trochanteric Nails

COMMON NAME: Rod, Fixation, Intramedullary and Accessories
CLASSIFICATION: Class II, 21 CFR 888.3020 Intramedullary fixation rod
DEVICE CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICE:
AOS Antegrade Femoral Nail (K123569, 5/24/13)
AOS Retrograde Femoral Nail (K132005, 9/10/13)
AOS Humeral Nail (K050241, 3/14/05)
AOS Proximal Humeral Nail (K090478, 3/26/09)
AOS Tibial Nail (K070444, 6/14/07)
AOS 12mm and 13mm Tibial Nails (K130625, 3/28/13)
AOS Trochanteric Nail (K021008, 6/20/02)
AOS ES Trochanteric Nail (K103533, 1/19/11)
AOS Solid Locking and Telescoping Lag Screw (K120148, 10/2/12)

DEVICE DESCRIPTION:
AOS Nails are intramedullary fixation devices for the temporary fixation of various types of fractures of long bones and are intended as load sharing devices which may be removed once the fracture has healed. The AOS Nail Systems consist of titanium intramedullary nails, proximal and distal locking screws, and end caps.

This Special 510(k) proposes the addition of gamma terminally sterilized nails, screws, and end caps.

INDICATIONS FOR USE:

The AOS Antegrade and Retrograde Femoral Nail are intended for use in intramedullary fixation of fractures of the femur to include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, and tumor resections, supracondylar fractures, including those with severe comminution and intraarticular extension, ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, nonunions and malunions, fractures resulting from osteoporosis.

The AOS Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures. The Humeral Nail is also intended to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.

The AOS Tibial Nail System is intended to provide temporary stabilization of various types of fractures, malunions, and nonunions of the tibia. The AOS Tibial Nail System is indicated for long bone fracture fixation of tibial fractures, which may include the following: transverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; nonunions, malunions, metaphyseal and epiphyseal fractures.

The AOS Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

SUBSTANTIAL EQUIVALENCE:

Information presented supports substantial equivalence of the AOS Nail Systems to the predicate devices. The proposed nails have the same indications for use, geometry and design, have the same fundamental scientific technology, and are made of the same material (Ti-6Al-4V ELI, per ASTM F136) as the predicate nails. As detailed in the submission,

the proposed nails only differ in sterilization method, which does not change the safety or effectiveness of the nails.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Incorporated
Attention: Kazunori Miyahara
Product Development Engineer
386 Beech Avenue, Unit B6
Torrance, California 90501

December 31, 2013

Re: K133081
Trade/Device Name: AOS Intramedullary Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 4, 2013
Received: December 5, 2013

Dear Kazunori Miyahara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

7. INDICATIONS FOR USE STATEMENT

Special 510(k) Premarket Notification
Indication for Use Statement
Intramedullary Nails

510(k) Number (if known): K133081

Device Name: AOS Intramedullary Nail

Indications for Use:

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The AOS Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures; proximal and distal non-unions and malunions and revisions procedures.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices